K081021

510(k) Summary per 21 CFR §807.92

AUG - 8 2008

Submitter's Name and Address	Boston Scientific Corporation (BSC) One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Christine Thomas Specialist, Regulatory Affairs Phone: 763-494-2942 Fax: 763-494-2981 e-mail: christine.thomas@bsci.com
Date Prepared	April 9, 2008
Proprietary Name(s)	Kinetix™ Guidewire
Common Name	Catheter Guidewire
Product Code	DQX
Classification of Device	Class II, 21 CFR Part 870.1330
Predicate Device	IQ™ Guidewire K040140 February 12, 2004
Device Description	The Kinetix™ Guidewires are two 0.014" PTCA guidewires utilizing a micro-slotted nitinol sleeve that replaces the traditional spring coil. The Kinetix Guidewires are similar in design and manufacture to the spring-coil IQ™ Guidewires (K040140 on February 12, 2004). The two distinct models are: Kinetix™ Guidewire – A guidewire with a soft, a-traumatic tip and a moderate rail support. Kinetix™ Plus Guidewire – A guidewire with a stiffer tip than the moderate support version and an intermediate rail support.

Intended Use of Device	Kinetix™ Guidewires are intended to facilitate placement and exchange of balloon dilatation catheters or other therapeutic devices during PTCA or PTA or other intravascular interventional procedures. The Kinetix Guidewires are not intended for use in the cerebral vasculature. The devices are provided non-pyrogenic, sterile, and intended for one procedure only.
Technological Characteristics	The Kinetix™ Guidewires utilize similar materials and methods of construction as the IQ™ Guide Wires (K040140, cleared on February 12, 2004). The significant difference in construction is the utilization of a micro-slotted Nitinol hypotube to replace the Inconel 625 (Nickel-Chrome alloy) spring coil. In addition there are two other material changes: the shaping ribbon material is changing from 304V Stainless Steel to Inconel 625 (Nickel-Chrome alloy) and the distal lubricious coating is changing from Silicone to Polyurethane.
Non-Clinical Test Summary	Testing and evaluation of the Kinetix™ Guidewires included torque response, tip prolapse, tip shapeability, radiopacity, marker location, lubricity, coating adherence/presence, tensile and shear, combined load, visual inspection, device compatibility, biocompatibility, and product shelf-life. Test results verified that the Kinetix™ Guidewires met all of the minimum requirements and are adequate for their intended use. The Kinetix™ Guidewires are considered substantially equivalent to guidewires currently marketed by Boston Scientific based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Christine Thomas
Regulatory Affairs Specialist
Boston Scientific Corporation
One Scimed Place
Maple Grove, MN 55311

AUG - 8 2008

Re: K081021
Trade/Device Name: Kinetix™ Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II
Dated: July 23, 2008
Received: July 24, 2008

Dear Ms. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-3150. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)	**K081021**
Device Name	Kinetix™ Guidewire
Indications For Use	Kinetix™ Guidewires are intended to facilitate placement and exchange of balloon dilatation catheters or other therapeutic devices during PTCA or PTA or other intravascular interventional procedures. The Kinetix™ Guidewires are not intended for use in the cerebral vasculature. The devices are provided non-pyrogenic, sterile, and intended for one procedure only.

Prescription Use ___X___ OR Over-The-Counter Use_____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bochner

(Division Sign-Off)
Division of Cardiovascular **Devices**

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